



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

July 18, 2017

CareFusion  
Joy Greidanus  
Regulatory Affairs Manager  
1500 Waukegan Road  
Waukegan, IL 60085

Re: K113854  
Trade/Device Name: Pleurx Peritoneal Catheter System  
Regulation Number: 21 CFR §876.5630  
Regulation Name: Peritoneal dialysis system and accessories  
Regulatory Class: II  
Product Code: PNG  
Dated: December 22, 2011  
Received: December 29, 2011

Dear Joy Greidanus:

This letter corrects our substantially equivalent letter of March 19, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



**CareFusion**

1500 Waukegan Road  
McGaw Park, Illinois 60085-6787  
847.473.7404  
FAX: 847.473.7790

**Indication for Use**

510(k) Number (if known): K113854

Device Name: Pleurx Peritoneal Catheter System

**Indications for Use:**

The Pleurx Peritoneal Catheter System is indicated for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, for the palliation of symptoms related to recurrent malignant ascites and for peritoneal placement only.

The Pleurx Drainage Bottle Kits and Drainage Line Set are indicated for use either with the Pleurx Peritoneal Catheter or Pleurx Pleural Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.

The Pleurx Drainage Bag Kit is indicated for use only with the Pleurx Peritoneal Catheter for intermittent drainage.

The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.

The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the peritoneal space.

Prescription Use X (Per 21 CFR 801.109) or Over-The Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A handwritten signature in black ink, appearing to read "John Deneen".

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and Urological Devices

510(k) Number K113854



MAR 19 2012

**510(k) SUMMARY K113854**

A summary of 510(k) safety and effectiveness information in accordance with 21CFR 807.92.

<b>SUBMITTER INFORMATION</b>	
Name	CareFusion
Address	1500 Waukegan Road MPWM, McGaw Park, IL 60085 USA
Phone number	(847) 473-7404
Fax number	(847) 473-7790
Establishment Registration Number	1423507
Name of contact person	Joy Greidanus
Date prepared	December 22, 2011
<b>NAME OF DEVICE</b>	
Trade or proprietary name	Pleurx Peritoneal Catheter System
Common or usual name	Catheter, peritoneal, long-term, indwelling
Classification name	Peritoneal dialysis system and accessories
Classification panel	Gastroenterology/Urology
Regulation	Class II per 21CFR §876.5630, Procode FJS
Product Code(s)	Multiple
Legally marketed device(s) to which equivalence is claimed	CareFusion Pleurx Peritoneal Catheter Kit and Drainage Kits: K051711 Bard Aspira Peritoneal Drainage System: K110396
Device description	The Pleurx Peritoneal Catheter System provides patients with a convenient method to relieve malignant ascites symptoms at home. The primary components of the Pleurx Catheter System are the Pleurx Peritoneal Catheter and the Pleurx Drainage Kits.



CareFusion

Intended use	<p>The Pleurx Peritoneal Catheter System is intended for intermittent, long term drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease, for the palliation of symptoms related to recurrent malignant ascites and for peritoneal placement only.</p> <p>The Pleurx Drainage Kits and Drainage Line Set are indicated for use with either the Pleurx Peritoneal Catheter or the Pleurx Pleural Catheter for intermittent drainage. The Drainage Line Kit is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle or other appropriate method.</p> <p>The Pleurx Drainage Bag is indicated for use only with the Pleurx Peritoneal Drainage Catheter for intermittent drainage.</p> <p>The Pleurx Dressing Kits are indicated for dressing of a catheter and exit site.</p> <p>The Pleurx Catheter Insertion Stylet is intended to aid in the percutaneous insertion of the Pleurx Catheter into the peritoneal space.</p>
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**SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE**

Characteristic	New Device	Predicates: CareFusion Pleurx Peritoneal Catheter Kit and Drainage Kits (K051711) Bard Aspira Peritoneal Catheter System (K110396)
Catheter Description	Internal: fenestrations, radiopaque markings & cuff External: valve	Same
Method	Percutaneously tunneled - indwelling	Same
Means of Drainage	Wall suction, water seal drainage system, portable suction, vacuum bottles or other appropriate method	Wall suction, water seal drainage system, vacuum bottles, syringe, drainage bag or other appropriate method



PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
Performance Test Summary	
Characteristic	Standard/Test/FDA Guidance
Biocompatibility	ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing
Residuals	ISO 10993-7:2008 Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
Performance	EN 1617:1997 Sterile Drainage Catheters and Accessory Devices for Single Use
Performance	EN 1618:1997 Catheters Other Than Intravascular Catheters – Test Methods for Common Properties
Performance	ANSI/AAMI/ISO 11607-1,2:2006 Packaging for Terminally Sterilized Medical Devices
Performance	ISO 11138-1,2:2006 Sterilization of healthcare products - Biological Indicators
Performance	ISO 11737-1,2:2006 Sterilization of Medical Devices – Microbiological Methods Part 1 & 2
Performance	ISO 11135:2007 Medical Device, Validation and Routine Control of Ethylene Oxide Sterilization
Performance	ISO 594-1:1986 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements
Performance	ISO 594-2:1998 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
N/A – No clinical tests were conducted for this submission	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
The results of the non-clinical tests show that the CareFusion Pleurx Peritoneal Catheter System meets or exceed all performance requirements, and are substantially equivalent to the predicate devices.	